

Notice of Allowability

Application No.

09/492,971

Examiner

Rita Mitra

Applicant(s)

VOQEL ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/23/2005.
2. ☒ The allowed claim(s) is/are 88,95,97 and 98.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Status of the Claims

A telephonic interview with Attorney on September 23, 2005 in response to the office action mailed April 12, 2005 is acknowledged. An informal proposal of amendments to the claims from Applicants were discussed and reached to an agreement as recited in the following Examiner's Amendment. Claims 88, 89 and 92-96 are currently pending and are under examination.

Response to Amendments and Remarks

Claim Rejections - 35 USC § 112, first paragraph

Rejection of claims 88, 89 and 92-96 are withdrawn in view of amendment to the claims in Examiner's amendment.

Claim Rejections - 35 USC § 112, second paragraph

Rejection of claims 88, 89 and 92-96 are withdrawn in view of amendment to the claims in Examiner's amendment.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Examiner's Amendment to the Claims

1-87. (Canceled)

88. (Amended) An imaging agent which comprises a polypeptide labeled with an imageable marker, such polypeptide having an amino acid sequence which

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comprises at least one fifth of the amino acid sequence of the N-terminal fibrin binding domain of naturally occurring fibronectin, ~~and having the amino acid sequence Gln-Ala-Gln-Gln (SEQ ID NO:39) or Met-Gln-Ala-Gln-Gln (SEQ ID NO:40)~~ commencing from the fourth amino acid shown in SEQ ID NO: 15, wherein the N-terminal fibrin binding domain comprises 262 amino acids commencing from the fourth amino acid shown in SEQ ID NO: 15, and wherein the polypeptide optionally has a methionine at the its N-terminus of the polypeptide, and wherein the polypeptide has a molecular weight less than 31kD.

89. ~~— (Canceled) A method for imaging a fibrin-containing substance which comprises contacting the fibrin-containing substance with the imaging agent of claim 88 under conditions such that the imaging agent binds to fibrin in the fibrin-containing substance, and imaging the bound imaging agent.~~

90-91. (Canceled)

92. ~~— (Canceled) The method of claim 89, wherein the fibrin-containing substance is within blood vessels of a subject and wherein contacting is performed by administering the imaging agent contained in a suitable carrier to the subject under conditions permitting the imaging agent to enter the blood vessels of the subject.~~

93. ~~— (Canceled) A method of claim 92, wherein the fibrin-containing substance is a thrombus.~~

94. ~~— (Canceled) A method of claim 92, wherein the fibrin-containing substance is atherosclerotic plaque.~~

95. (Amended) ~~An~~ The agent of claim 89 ~~88~~, wherein the marker is a radioactive isotope, an element which is opaque to X-rays, or a paramagnetic ion.

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96. ~~(Canceled) A method of claim 89, wherein the imaging is carried out using a gamma camera.~~
97. (New) The agent of claim 95, wherein the marker is a radioactive isotope.
98. (New) A purified polypeptide having an amino acid sequence which comprises at least one fifth of the amino acid sequence of the N-terminal fibrin binding domain of naturally-occurring fibronectin commencing from the fourth amino acid shown in SEQ ID NO: 15, wherein the N-terminal fibrin binding domain comprises 262 amino acids commencing from the fourth amino acid shown in SEQ ID NO: 15, and wherein the polypeptide optionally has a methionine at its N-terminus, and wherein the polypeptide has a molecular weight less than 31kD.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Gary Gershik on September 27, 2005.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The prior art of record does not teach or suggest an imaging agent comprising a polypeptide having an amino acid sequence which comprises at least one fifth of the amino acid sequence of the N-terminal fibrin binding domain of naturally occurring fibronectin, wherein the N-terminal fibrin binding domain comprises 262 amino acids commencing from the fourth amino acid of SEQ ID NO: 15 and wherein the polypeptide has a molecular weight less than 31 kD. Therefore the claims are allowable over the art of record. .

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany

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the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 88, 95, 97 and 98 are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954.

The examiner can normally be reached on M-F, 10:00 am-7:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

September 30, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER